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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,877	12/09/2003	Darren A. Janzig	1023-335US01	4792

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
05/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/730,877	JANZIG ET AL.	
	Examiner	Art Unit	
	ALYSSA M. ALTER	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "implanted on the cranium" to –configured to be implanted on the cranium--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-15, 17-32, 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 22 recite the limitation of a "second profile of the housing". However, there is insufficient antecedent basis for this limitation in the claim since there is no description in the specification for a "second profile". Further clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-7, 8-9, 15, 17-19, 20-22, 29, 31-32 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinberg et al. (US 5,144, 946). Weinberg et al. discloses an implantable medical device with a housing that contains a double-sided substrate (i.e. a circuit board) that has a plurality of integrated components on one side

of the circuit board, see figure 4A and a plurality of discrete components on the other side of the circuit board, see figure 4B.

In regards to the integrated components, Weinberg et al. discloses that figure 4A has "electronic components 56 (including, diodes, transistors, and other integrated circuits)" (col. 5, lines 40-42). In regards to the discrete components, Weinberg et al. discloses that figure 4B has "tantalum capacitors 57" (col. 5, line 45).

Furthermore, as depicted in figure 4A and 4B, the electrical components are arranged in a non-linear profile with respects to the second profile of the housing since both the discrete and integrated components vary in height. Since they are made to fit in the housing and are thus "based" on the profile.

As to claims 3-5, Weinberg et al. depicts the telemetry coil 59 encircling the circuit board in figure 4B.

As to claim 6, when the medical device is implanted within the body there will be a surface of the circuit board as well as a second plane that will necessarily be closer to the cranium with respects to the rest of the medical device.

As to claim 9, as depicted in figure 4A, the height of the components increase from the edge of the board to the center of the board.

As to claim 15 and 17-18, as seen in figure 2, the feedthroughs 24 are located at a non-parallel and non-perpendicular angle relative to a major surface of the housing.

As to claim 19, figure 2 also depicts a battery 16 located within a separate housing from the discrete and integrated components.

As to claims 20-21, the functional language and introductory statement of intended use of claims 20-21 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Weinberg et al utilizes an implantable stimulation device as claimed by the Applicant, Weinberg et al. is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Weinberg et al. from utilizing the implantable stimulation device to function as a neurostimulator and stimulate the brain. Therefore, the implantable stimulation device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

Furthermore, as to claim 21, It has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

2. Claims 1, 9-10, 15, 18-21, 32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinberg (US 5,674,260). Weinberg discloses an "electronics package 30 is a hybrid circuit structure containing various integrated circuits which are vertically stacked at different positions to create a multi-level circuit structure"(col. 3, lines 15-18). Figure 3 displays "a group of integrated circuits 34, which may be random access memory (RAM) chips, mounted atop a platform 36. Underneath the platform 36 are additional electronic components (not shown) which are mounted to a substrate 38 and which communicate with the integrated circuits 34. An additional integrated circuit 40 is mounted directly to the substrate 38 and is not covered by the platform 36" (col. 3,

lines 19-26). The examiner considers the substrate 38 and the platform 36 to be a circuit board.

Since the integrated circuits 34 are mounted on a platform, which the examiner considers to be part of the circuit board, compared to integrated circuit 40, they are in a non-linear profile based on a second profile of the housing. Since they are made to fit in the housing and are thus "based" on the profile.

Since Weinberg discloses on col. 3, lines 21-24, "underneath the platform 36 are additional electronic components (not shown) which are mounted to a substrate 38 and which communicate with the integrated circuits 34". The examiner considers the additional electrical components 72, as depicted in figure 6, to be discrete components since Weinberg has discloses the additional components communicate with the integrated circuits and thus are not integrated circuits themselves.

As to claim 9, the height of the integrated circuits increase from an edge towards the center. A replication of figure 3 is included and displays the integrated circuit 40 on the edge of the first surface is at a smaller height than the integrated circuit 34 towards the center of the first surface.

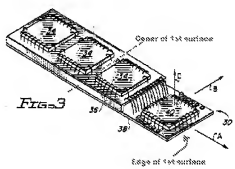
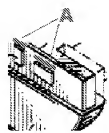


FIG. 3

As to claim 10, in the indicated portion of figure 6 at right, the discrete components 72, are further magnified. The highlighted portion indicates the two heights of components 72. Labeled as "A", the heights decrease from the edge of the second surface of the circuit board towards the center of the circuit board.



As to claims 15, 18, 32-33 and 35, figure 5 displays "the resistor board 68 in turn communicates with an electronics package (not shown) via wires 70"(col. 4, lines 24-26). Therefore, it follows that there is a feedthrough located in the electronic package 30 to enable wire connection to the resistor board via wires 70.

Furthermore, as seen in the replication of figure 5 depicted on the right, the box placed around a portion of the implantable medical device indicates a "major surface of the housing" that is at a "non-parallel, non-perpendicular angle" from the feedthrough.

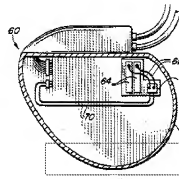


FIG. 5

As to claim 19, the battery 74 is depicted in figure 6.

As to claims 20-21, the functional language and introductory statement of intended use of claims 20-21 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Weinberg utilizes an implantable stimulation device as claimed by the Applicant, Weinberg is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Weinberg from utilizing the implantable stimulation device to function as a neurostimulator and stimulate the brain. Therefore, the implantable stimulation device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

Furthermore, as to claim 21, It has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability

to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

3. Claims 22-23, 25-26, 28-32 and 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Engmark et al. (US Patent Publication 20040082977 A1). Engmark et al. discloses a implantable medical device with an antenna coil 32, "electrical circuitry 22 typically contains numerous interconnected electrical components 23 mounted on circuit board 27 so as to form electrical module 28"(page 2, paragraph 21).

As to claim 22, as depicted in figure 8, from the top view of the implantable system, the telemetry coil 32 is located in the second plane and is substantially uneclipsed by the circuit board 27 located in the first plane, wherein the two planes are parallel to each other, thus resulting in no eclipse. In a perpendicular direction to either the first or second plane.

As to claims 25-26, as previously mentioned, the electrical components 23 are mounted on circuit board 27 to form the electrical module 28. The examiner considers the electrical components to be the integrated circuits and discrete components.

Furthermore, figure 8 depicts the thickness of the circuit board and components and housing. Engmark et al. discloses on page 4, paragraph 39, "It will be noted in FIG. 8 that antenna coil 32 is spaced apart from housing 11 by distances 60, 61 and from substrate 27 by distance 62. It is desirable that distance 60 between a principal plane of coil 32 and a principal plane of housing 11 and distance 62 between a principal plane of coil 32 and a principal plane module substrate 27 be usefully approximately 0.5 mm or larger, conveniently approximately 0.7 mm or larger, and preferably approximately

0.76 mm or larger. The efficiency of antenna coil 32 degrades as the plane of coil 32 approaches closer to the plane of conductive housing 11 and/or the conductive portions of module substrate 27. The distances between the corners of coil 32 and housing 11, e.g., distance 61, is less important and can be smaller than distances 60, 62".

As to claim 28, Engmark et al. teaches on page 1, paragraph 4, the use of "a circuit board or flexible tape".

As to claim 29, the battery 20 is depicted in figure 7.

As to claim 30, Engmark et al. discloses "implantable medical devices such as pacemakers, defibrillators, neuro-stimulators, and the like"(page 1, paragraph 2).

As to claims 30-31, the functional language and introductory statement of intended use of claims 30-31 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Engmark et al. utilizes an implantable medical device as claimed by the Applicant, Engmark et al. is therefore capable of being used as an implantable neurostimulator to stimulate the brain. In addition nothing prevents Engmark et al. from utilizing the implantable medical device to function as a neurostimulator and stimulate the brain. Therefore, the implantable medical device is capable of being utilized as an implantable neurostimulation device to stimulate the brain.

Furthermore, as to claim 31, It has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claims 32 and 34-35, "Circuit board 27 of module 28 includes metal contact areas 29 that are conveniently electrically coupled to inner portions 17 of one or more electrical feed-throughs 16 of device 10"(page 2, paragraph 21). "One or more feed-through connectors permit electrical communication to and from the electrical components and circuitry contained within the housing while at the same time maintaining the hermeticity of the device" (page 1, paragraph 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 10-14 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg et al. (US 5,144, 946). Weinberg et al. discloses the claimed invention except for arrangement of discrete components. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the positioning of the discrete components, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70* (see MPEP 2144.04). Furthermore, rearranging of the discrete components would provide the predictable results of having a narrower profile of the medical device. Such a modification is well known in the art since it occupies less space in the patient and is less noticeable once implanted.

As to claim 11-12 and 25-26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size of the housing and the components as taught by Weinberg et al., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233].

Furthermore, small components would provide the predictable results of having a narrower profile of the medical device. Such a modification is well known in the art since it occupies less space in the patient and is less noticeable once implanted.

As to claims 13-14, Weinberg et al. discloses the claimed invention except for the circuit board comprising flex tape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the circuit board with flex tape, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07). Furthermore, modifying the system with flex tape would provide the predictable results of arranging the components in the medical device to have substrate capable of conforming to the interior dimensions of a medical device. Additionally a flexible circuit board would enable the circuit board to be concave in at least one axis.

2. Claims 11-14 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg (US 5,674,260). Weinberg discloses the device as claimed but fails to teach the specific thickness for the housing and components. It would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the size of the housing and the components as taught by Weinberg, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233]. Furthermore, small components would provide the predictable results of having a narrower profile of the medical device. Such a modification is well known in the art since it occupies less space in the patient and is less noticeable once implanted.

As to claim 14, Weinberg discloses the claimed invention except for the circuit board comprising flex tape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the circuit board with flex tape, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07). Furthermore, modifying the system with flex tape would provide the predictable results of arranging the components in the medical device to have substrate capable of conforming to the interior dimensions of a medical device. Additionally a flexible circuit board would enable the circuit board to be concave in at least one axis.

3. Claims 8 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg et al. (US 5,144, 946) or Weinberg (US 5,674,260) in view of Bardy et al. (US Patent Publication 20020042634 A1). Weinberg et al. and Weinberg discloses the device substantially as claimed but fail to teach a curved housing. Bardy et al. discloses a curved housing to better fit the contours of the patient's body once implanted. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the housing as taught by Weinberg et al. or Weinberg with the curved housing as taught by Bardy et al. in order to provide the predictable results of ensuring the medical device will fit the contours of the human body once implanted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762